

Notice of Allowability

Application No.

09/782,378

Examiner

Gerald G Leffers Jr., PhD

Applicant(s)

HEARING ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the amendment of 11/1/2004.
2. ☒ The allowed claim(s) is/are 11-13, 20-23 (now claims 1-7).
3. ☒ The drawings filed on 12 February 2001 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Peter Carroll on 1/19/2005.

The application has been amended as follows:

In the claims:

In claim 23, line 2, the term "A540-derived" has been deleted and replaced with the term --A549-derived--.

Claims 6-10 have been cancelled as being directed to a nonelected invention, said election being made without traverse (see the response filed 7/22/2002).

Reasons for Allowance

The following is an examiner's statement of reasons for allowance: applicants' amendment of the claims has overcome the remaining grounds of rejection from the previous office action. The closest prior art for the remaining claims is Leiber et al (Journal of Virology, November 1999, Vol. 73, No. 11, pages 9314-9324; cited on the IDS filed 4/9/01 as reference no. 25). Leiber et al teaches a similar method for generating minimal adenovirus vectors to that

which is recited in the allowed claims, but differs in important ways. For example, the starting AAV/Ad hybrid taught by Leiber et al does not comprise an AAV terminal repeat on the 3' end of the gene of interest. In the constructs taught by Leiber et al, the single AAV terminal repeat is on the 5' end of the gene of interest (e.g. see Figure 1, Ad.AAV1- Δ ITR). More importantly, the reference does not teach the use of a cell that expresses of one or more rep proteins to facilitate generation of the minimal Adenovirus vectors (see instant claim 12, part (a)-(ii)). Thus, the Leiber et al reference does not anticipate the claimed method.

Nor does the reference make obvious the claimed method. Leiber et al teach, "Taken together, our data show that the presence of two intact AAV ITRs flanking a reporter gene cassette was required for the effective formation of Δ ad.AAV genomes. This process did not efficiently occur with partially deleted ITRs or oligo-dC and oligo-dG stretches flanking the expression cassette." (see page 9317, column 1, 4th paragraph). This statement, while not a teaching away in the sense of teaching the claimed invention would not work, does have the effect of raising the bar for any suggestion to modify the teachings of Leiber et al to arrive at the claimed invention. For example, there is a related article by the same group published in the same journal issue (Steinwaerder, et al. pages 9303-9313; cited on the IDS filed 4/9/01 as reference no. 53) that teaches a similar recombination scheme for an adenoviral construct having a similar overall structure as the construct of the instant claims (i.e. compare Ad.Ins1/3a of reference Figure 1A to the construct of claim 12(a)-(i)). However, the reference differs from the recited methods in that the Steinwaerder et al construct does not use AAV ITRs (i.e. the constructs are not AAV/Ad hybrids). Nowhere does Steinwaerder et al or Leiber et al suggest the use of the particularly claimed AAV/Ad hybrid of the instant claims or the use of cells that

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express one or more AAV rep proteins to produce the recited product vectors. Therefore, the instant claims are not obvious over Leiber et al or Leiber et al in view of Steinwaerder et al.

Conclusion

Claims 11-13 and 20-23 are allowed (now claims 1-7).

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G Leffers Jr., PhD whose telephone number is (571) 272-0772. The examiner can normally be reached on 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gerald G Leffers Jr., PhD
Primary Examiner
Art Unit 1636

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GERRY LEFFERS
PRIMARY EXAMINER